

FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)  
Anti-Infective Drugs Advisory Committee Meeting  
Hilton Washington DC/Silver Spring MD  
April 29, 2010

**AGENDA**  
**OPEN SESSION**

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*The committee will discuss the efficacy and safety of new drug application (NDA) 21-242, artesunate rectal suppositories, submitted by the World Health Organization, for the proposed use as a single dose for the initial treatment of patients with acute malaria who cannot take medication by mouth and for whom injectable treatment is not available.*

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8:00 a.m.	<b>Call to Order &amp; Introduction of Committee</b> Committee Chair
	<b>Conflict of Interest Statement</b> Minh Doan, Pharm.D., Designated Federal Officer
8:10 a.m.	<b>Introduction</b>
8:20 a.m.	<b><u>Sponsor's Presentations</u></b> World Health Organization
9:35 a.m.	Questions/Clarifications for Sponsor
10:05 a.m.	Break
10:20 a.m.	<b><u>FDA Presentations</u></b>
11:30 a.m.	Questions/Clarifications for FDA
12:00 p.m.	Lunch
1:00 p.m.	Open Public Hearing
2:00 p.m.	Questions/Clarifications for Sponsor and FDA
2:30 p.m.	Charge and Questions to the Committee
5:00 p.m.	Adjourn